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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/813,345 | 03/20/2001 | Derek David Smith | 180.0002 0102 | 2898 |

26813 7590 04/08/2003

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| EXAMINER |
|---|
| JIANG, DONG |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | 14 |

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/813,345 | SMITH ET AL. | |
| | Examiner | Art Unit | |
| | Dong Jiang | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-26 and 29-55* is/are pending in the application.

4a) Of the above claim(s) *34,35 and 48-53* is/are withdrawn from consideration.

5)☒ Claim(s) *21-26,29-33 and 36-47* is/are allowed.

6)☒ Claim(s) *54 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *21-26 and 29-55* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED OFFICE ACTION

Applicant's amendment in paper No. 13, filed on 26 December 2002 is acknowledged and entered. Following the amendment, claims 29, 32, 33, 45, 46, 48, 50, 51 and 53 are amended, and the new claims 54 and 55 are added.

Currently, claims 21-26, and 29-55 are pending, and claims 21-26, 29-33, 36-47, 54 and 55 are under consideration.

With respect to Applicants further argument on the restriction requirement, as the restriction requirement was deemed proper and was therefore made FINAL in the last Office Action for the reasons of record, further traversal is not timely. Applicants only recourse in this matter is to petition under 37 CFR 1.144.

***Withdrawal of Objections and Rejections:***

The rejection of claims 21-26, 29-33, and 36-47 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The rejection of claims 21-26, 29-33, and 36-47 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendments.

***Formal Matters:***

Claim 31 remains objected to for encompassing a non-elected species, SEQ ID NO:1.

Claim 55 is objected under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. "Z" in the claim is defined as an antagonist of CGRP. As claim 55 depends from claim 54, in which Z is defined as a vasoactive peptide, it is not further limiting claim 54 because the term "vasoactive peptide" is referred to, in the specification, peptides that are capable of causing vasoconstriction or vasodilatation of blood vessels (page 8, lines 13-14). However, an antagonist of CGRP is not vasoactive as it is not capable of inducing either vasoconstriction or vasodilatation. An antagonist is "a substance that tends to

nullify the action of another, as a drug that binds to a cell receptor *without eliciting a biological response* (Dorland's Illustrated Medical Dictionary).

***Objections and Rejections under 35 U.S.C. 112:***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is indefinite because it is unclear what "a vasoactive peptide" refers to. The specification provides two definitions for the term at pages 8 and 11, respectively, and they are different from each other. As such, the metes and bounds of the claim cannot be determined.

The remaining claim is rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54 and 55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the same reasons applied to claims 21-26, 29-33, and 36-47, set forth in the last Office Action, paper No. 12, mailed on 26 September 2002, at pages 4-5. The relevant issues of the rejection from the previous office action are reiterated below.

With respect to claim 54, the claim is directed to a method for inhibiting CGRP binding to its receptors with a composition, and the active ingredient of the composition used in the method is "Z", a vasoactive peptide. The term "vasoactive peptide" is referred to, in the specification, peptides that are capable of causing vasoconstriction or vasodilatation of blood vessels (page 8, lines 13-14). The specification merely teaches antagonists of CGRP, which are

fragments of CGRP, and provides no support that any "vasoactive peptide" can be used in such a method because, by definition, an antagonist is "a substance that tends to nullify the action of another, as a drug that binds to a cell receptor *without eliciting a biological response* (Dorland's Illustrated Medical Dictionary). Thus, an antagonist of CGRP can be neither a vasoconstrictor nor a vasodilator, therefore, it must *not* be a "*vasoactive* peptide". As claim 54 requires "a vasoactive peptide", and the specification provides no instruction/guidance as to how to make such "a vasoactive peptide", nor working examples of any vasoactive peptide which can be used in the claimed method, it is not predictable that any vasoactive peptide would inhibit CGRP binding to its receptor. Therefore, undue experimentation is required in order to search for a *vasoactive* peptide that would be within the limitations of the claim. Additionally, it is unclear what is the rational to use a vasodilator in a method for inhibiting CGRP binding to its receptors, as CGRP is a vasodilator.

Due to the large quantity of experimentation necessary to determine a vasoactive peptide that would be within the limitations of the claim, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention in which an agonist may be used in a method for inhibiting receptor-ligand binding, the state of the prior art has not established that any vasoactive peptide would be able to inhibit CGRP binding to its receptor, and the breadth of the claims which embrace a broad class of structural variants, undue experimentation would be required of the skilled artisan to make and the claimed invention in its full scope.

With respect to claim 55, the claim is dependent from claim 54, in which Z is defined as a vasoactive peptide. However, "Z" in claim 55 is an antagonist of CGRP. For the reasons addressed above, an antagonist of CGRP can be neither a vasoconstrictor nor a vasodilator, therefore, is not a "*vasoactive* peptide". As claim 54 requires Z to be a "vasoactive peptide", claim 55 is not enabled for the claimed method.

Applicants argument, filed on 26 December 2002 (paper No. 13) has been fully considered, but is not deemed persuasive for reasons below.

At page 8 of the response, the applicant argues that the specification provides adequate guidance for the preparation of peptide Z and the antagonists of claims 32 and 33, and thus it

would not require undue experimentation to make and use the antagonist peptides of the invention. This argument is not persuasive because this issue is not about how to make and use the antagonist peptides, rather, the issue here is that the original claim 29 defines Z as "a vasoactive peptide", the specification merely teaches the antagonists, which are not *vasoactive* peptides, and therefore, the specification does not teach how to make and use a vasoactive peptide.

At page 9 of the response, the applicant argues that as noted in the specification (page 8, lines 18-20), a variety of vasoactive peptides that function as CGRP antagonists are known in the art and these include CGRP receptor-binding peptide fragments of CGRP, and peptides of adrenomelullin and amylin, and thus that an antagonist peptide is a vasoactive peptide. This argument is not persuasive because, upon further reviewing the art, the Examiner notices the fact that CGRP, adrenomelullin, and amylin are vasodilators ("vasoactive"), and certain fragments of CGRP, adrenomelullin, or amylin, *but not* CGRP, adrenomelullin, and amylin molecules themselves, are antagonists, which cause neither vasoconstriction nor vasodilation. Therefore, it is incorrect to assert that an antagonist peptide is a vasoactive peptide.

***Conclusion:***

Claims 21-26, 29-33, 36-47 are allowable.

***Advisory Information:***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

DJ
4/3/03